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JCS42 U.S. PTO

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PATENTS, TRADEMARKS  
AND COPYRIGHTS

July 17, 1998

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Commissioner of Patents & Trademarks  
Washington, DC 20231

Re: New U.S. Patent Application  
Continuation-in-Part of Serial No. 08/781,308  
Title: METHOD OF MAKING FREE ACIDS FROM POLYSACCHARIDE SALTS  
Case Docket No.: 281-28

Dear Sir:

Transmitted herewith for filing is the patent application identified above. Enclosed are:

- 1) Specification, claims, and abstract (17 pages)
- 2) Declaration and Power of Attorney (unsigned)
- 3) Response to Rejection in Parent Application (2 pages)
- 4) Declaration of Ellington M. Beavers under Rule 132 (5 pages)

This application is being filed without a filing fee, and without a signed Declaration, pursuant to the provisions of 37 CFR \$1.53(b). The filing fee and signed papers, and the surcharge for late filing, will be submitted later. The names of the inventors are set forth in the unsigned Declaration.

Please direct correspondence, in this matter, to the undersigned.

Sincerely,

*William H. Eilberg*

William H. Eilberg  
Registration No. 28,009  
Attorney for Applicants

Via Express Mail  
Label No. EE369870954US  
WHE/st  
Enc.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. Not Yet Known  
Filed: Not Yet Known  
Continuation-in-Part of: Serial No. 08/781,308  
Inventors: Ellington M. Beavers et al  
Title: METHOD OF MAKING FREE ACIDS  
FROM POLYSACCHARIDE SALTS  
File No.: 281-28

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RESPONSE TO REJECTION IN PARENT APPLICATION

Hon. Commissioner of Patents & Trademarks  
Washington, DC 20231

Dear Sir:

Applicants submit this paper in response to the rejection of claims made in the parent application (Serial No. 08/781,308). Some of the claims in this continuation-in-part application are the same as claims rejected, and cancelled, in the parent case.

The Examiner in the parent case rejected the product-by-process claims, relying on the patents to Huang and Della Valle, and also citing Cipriano and Ochoa Gomez.

Applicants submit that the free hyaluronic acid produced by the process of the present invention is demonstrably different from what is obtained by the methods of the prior art.

Attached is a Declaration of Ellington M. Beavers, one of the inventors herein, explaining several experiments conducted. The details of the experiments will not be repeated here. The experiments show that the processes exemplified by Della Valle, Cipriano, and Ochoa Gomez all yield a product which is hemolytic and cytotoxic, and therefore not suitable for use on medical devices which are to be implanted in the body. By contrast, the product made by the process of the present invention does not suffer

from the above-described disadvantages.

The processes of the above-cited patents all involve passing sodium hyaluronate through an anionic membrane. The membrane used in the present invention is non-ionic and electrically neutral. Some of the claims presented in this new application emphasize this difference.

The patent to Huang states that pure hyaluronic acid is used, but does not disclose how the hyaluronic acid was made. However, in view of the experimental evidence set forth in the attached Declaration, it is clear that not all hyaluronic acid is alike, and that the characteristics of the product are greatly affected by the method of manufacture. Thus, absent a suggestion, in Huang, of the use of the present method to make the product, the patent to Huang cannot be deemed suggestive of the present invention.

In summary, none of the cited references discloses or suggests a method of making free hyaluronic acid which is non-hemolytic, and which is not cytotoxic. Applicants are believed to be the first to provide a pure form of hyaluronic acid, which is suitable for coating medical devices to be implanted in the body.

For the reasons given above, Applicants submit that all claims are allowable, and request early favorable action by the Examiner.

Respectfully submitted,

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